

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Date: December 4, 2008

RANDALL J. HUEBNER and BENONE TARCAU

Docket No. ACM 352

Serial No. : 10/712,202

Group Art Unit 3733

Filed : November 12, 2003

Examiner Jerry L. Cumberledge

For : BONE SCREWS

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
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Sir:

BRIEF OF APPELLANTS

This Brief is presented in opposition to the rejection of claims 5–9, 11, 13–15, 17–26, 28, and 31–40 in the Final Office Action dated June 11, 2008.

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I. REAL PARTY IN INTEREST

The real party in interest is Acumed LLC, a limited liability company established under the laws of Delaware and having a place of business at 5885 NW Cornelius Pass Road, Hillsboro, Oregon 97124.

II. RELATED APPEALS AND INTERFERENCES

There are no known related appeals or interferences.

III. STATUS OF CLAIMS

The status of the claims is as follows:

Canceled – claims 1–4, 10, 12, 16, 27, 29, and 30.

Rejected – claims 5–9, 11, 13–15, 17–26, 28, and 31–40.

The claims at issue in this appeal consist of all rejected claims listed above.

IV. STATUS OF AMENDMENTS

No amendments to the claims have been proposed or entered after the Final Office Action dated June 11, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The following summary is a concise explanation of the subject matter defined in each of the independent claims under appeal, namely, claims 5, 21, 28, and 35. The subject matter is exemplified by accompanying references to passages of the specification and elements of the drawings.

Independent claim 5 is directed to a method of compressing a bone 22 (see, e.g., page 2, lines 1-20, for background; Figure 1). The method comprises selecting a bone screw 20 (e.g., Figures 1-3). The bone screw (20) includes a shank 52 that includes a thread 76 disposed externally for threaded engagement with bone 22 (page 5, line 20, to page 6, line 2; Figures 1 and 3). The shank (52) defines a long axis 38 and a direction of advancement into bone 22 (page 4, lines 18-21). The bone screw (20) also includes a head 50 connected to the shank (52) and defining a plurality of shoulders 60 disposed at spaced positions generally along the head (50)(page 5, lines 9-15; Figures 2 and 3). Each shoulder 60 faces generally toward the direction of advancement and extends partially or completely around the head (50) to define a respective plane disposed orthogonally to the long axis (38)(page 10, line 21, to page 11, line 5; Figures 2 and 3). The method also comprises installing the bone screw (20) as a unit in a bone 22 such that a portion 26 of the bone (22) near the head (50) is engaged by two or more of the shoulders (60) and is urged toward a portion 28 of the bone (22) near the shank (52)(page 4, lines 3, 4, and 11-21; page 5, lines 11-15; Figures 1 and 2).

Independent claim 21 is directed to a method of compressing a bone 22 (see, e.g., page 2, lines 1-20, for background; Figure 1). The method comprises selecting a

bone screw 20 (e.g., Figures 1-3). The bone screw (20) includes a shank 52 that includes a proximal region 78, a distal region 80, and a thread 76 disposed externally for threaded engagement with bone 22 and restricted to the distal region (80)(page 5, line 20, to page 6, line 2; Figures 1 and 3). The bone screw (20) also includes a head 50 connected to the shank (52) and spaced from the thread (76) by the proximal region (78)(page 5, lines 1-9 and line 20, to page 6, line 2; Figures 2 and 3). The head (50) defines a plurality of spaced shoulders 60 disposed generally along the head (50)(page 5, lines 9-15; Figures 2 and 3). Each shoulder 60 extends in a respective plane to describe at least an arc of a circle (page 10, line 21, to page 11, line 5; Figures 2 and 3). The method also comprises installing the bone screw (20) as a unit in a bone 22 such that a portion 26 of the bone (22) near the head (50) is engaged by two or more of the shoulders 60 and is urged toward a portion 28 of the bone (22) near the shank (52)(page 4, lines 3, 4, and 11-21; page 5, lines 11-15; Figures 1 and 2).

Independent claim 28 is directed to a method of compressing a bone with a bone screw (see, e.g., page 2, lines 1-20, for background). The method comprises forming a hole 30 in the bone (22)(page 4, lines 14 and 15; page 16, line 19, to page 20, line 9; Figure 1). The method also comprises selecting a bone screw 20 having a shank 52 and a head 50 connected to the shank 52 (page 5, lines 1-9; Figures 2 and 3). The head (50) defines a plurality of shoulders 60 disposed at spaced positions generally along the head (50)(page 5, lines 9-15; Figures 2 and 3). Each shoulder 60 faces generally toward the direction of advancement and extends partially or completely around the head (50) to define a respective plane disposed orthogonally to the long axis (38)(page 10, line 21, to page 11, line 5; Figures 2 and 3). The method further

comprises advancing first the shank (52) and then the head (50) of the bone screw (20) into the hole (30) via threaded engagement of the shank (52) with the bone (22) such that a portion 26 of the bone (22) near the head (50) is engaged by two or more of the shoulders 60 and is urged toward a portion 28 of the bone (22) near the shank (52)(page 4, lines 3, 4, and 11-21; page 5, lines 11-15; Figures 1 and 2).

Independent claim 35 is directed to a method of compressing a bone (see, e.g., page 2, lines 1-20, for background). The method comprises selecting a bone screw 20 including a shank 52 that includes a thread 76 disposed externally for threaded engagement with bone 22 (page 5, line 20, to page 6, line 2; Figures 1 and 3). The shank (52) defines a long axis 38 and a direction of advancement into bone (page 4, lines 18-21). The bone screw (20) also includes a head 50 connected to the shank (52) and including a plurality of spaced shoulders 60 of different diameter (page 5, lines 9-15; page 9, lines 3-6; Figures 2 and 3). Each shoulder 60 faces generally toward the direction of advancement and extends partially or completely around the long axis (38) in a respective path defining a plane (page 10, line 21, to page 11, line 5; Figures 2 and 3). The method also comprises installing the bone screw (20) as a unit in a bone 22 such that a portion 26 of the bone (22) near the head (50) is engaged by two or more of the shoulders 60 and is urged toward a portion 28 of the bone (22) near the shank (52)(page 4, lines 3, 4, and 11-21; page 5, lines 11-15; Figures 1 and 2).

Specific references to portions of the application are provided with the understanding that nonreferenced portions of the application also may be relevant. As such, it should be understood that the claims are not limited by the particular references made above, but rather are supported by the entirety of the disclosure.

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Appellants request review of the rejection of claims 5–9, 11, 13–15, 17–26, 28, and 31–40 in the Final Office Action dated June 11, 2008, under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,743,912 to Lahille et al. (“Lahille”) in view of U.S. Patent No. 5,653,765 to McTighe et al. (“McTighe”).

VII. ARGUMENT

The Examiner has improperly rejected each of claims 5–9, 11, 13–15, 17–26, 28, and 31–40 under 35 U.S.C. § 103(a) as being obvious over a combination of Lahille and McTighe. When the claims are reviewed under the current standards for obviousness as set forth by the Federal Courts and the Board of Patent Appeals and Interferences, the impropriety of the rejections becomes clear.

A. The Legal Standard for Obviousness under 35 U.S.C. § 103

Obviousness is a question of law based on (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. See *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). “In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art.” *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). “If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent.” *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

In order to establish a *prima facie* case of obviousness there must be a “clear articulation of the reason(s) why the claimed invention would have been obvious.” MPEP § 2142, 8th Edition, August 2001, Latest Revision July 2008. The Federal Circuit has stated that “rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational

underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR v. Teleflex*, 550 U.S. 398, 82 USPQ2d 1385, 1396 (quoting Federal Circuit statement with approval).

A number of circumstances preclude modification of a reference to establish *prima facie* obviousness. For example, if the reference teaches away from the proposed modification then there is no *prima facie* obviousness. See *In re Young*, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991). In addition, there is no *prima facie* obviousness if the proposed modification changes the principle of operation of the reference. See *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Furthermore, the MPEP states that “[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).” MPEP § 2143.01(V), 8th Edition, August 2001, Latest Revision July 2008.

B. Claims 5–9, 11, 13–15, and 17–20

Each of claims 5–9, 11, 13–15, and 17–20 was rejected as being obvious over a combination of Lahille and McTighe. Appellants disagree and request reversal of the rejections for at least the reasons set forth below.

1. No Prima Facie Obviousness for Claim 5

Independent claim 5 reads as follows:

5. A method of compressing a bone, comprising:
selecting a bone screw including
a shank including a thread disposed externally for threaded
engagement with bone, the shank defining a long axis and a direction of
advancement into bone, and

a head connected to the shank and defining a plurality of shoulders disposed at spaced positions generally along the head, each shoulder facing generally toward the direction of advancement and extending partially or completely around the head to define a respective plane disposed orthogonally to the long axis; and
installing the bone screw as a unit in a bone such that a portion of the bone near the head is engaged by two or more of the shoulders and is urged toward a portion of the bone near the shank.

Claim 5 is not *prima facie* obvious over the cited references because (a) the Examiner has not provided a rational explanation for why one of skill in the art would modify Lahille with McTighe in the manner proposed, (b) Lahille teaches away from the proposed modification, (c) the proposed modification changes the principle of operation of Lahille, and (d) the proposed modification forces an element (an ellipsoidal collar) from McTighe to take on a new function and assume a new shape, thereby rendering the element unsatisfactory for its intended purpose. The following subsections explain the proposed modification (subsection 2) and support appellants' assertion of a failure to establish *prima facie* obviousness (subsections 3-6).

2. Lahille Modified by McTighe

This subsection summarizes the disclosures of Lahille and McTighe and describes the modification of Lahille proposed by the Examiner.

Lahille involves an implant for the upper femur, which is used to hold together bone fragments thereof. The reference depicts first, second, and third embodiments of the implant, for example, in Figures 1, 6-8, and 10. However, the Examiner relied on the second embodiment (hereinafter, "the second implant") of Figures 6-8 to make the

rejection. Figure 7, which is reproduced below to facilitate review, illustrates an exploded, longitudinal sectional view of the second implant.

The second implant includes an elongate rectilinear body 3 and an end-piece 4 that is received on body 3 from an end thereof. Body 3 and end-piece 4 each form an external thread for threaded engagement with bone. After assembly of body 3 with end-piece 4, the end-piece is held on body 3 in a biased configuration. In particular, a spring 5 is received in a bore of end-piece 4 and compressed by a plug 6 threaded onto a screwthreaded distal portion 33 of body 3. The compressed spring urges the external thread of body 3 toward the external thread of end-piece 4, to provide compression of bone fragments engaged by the body and end-piece.

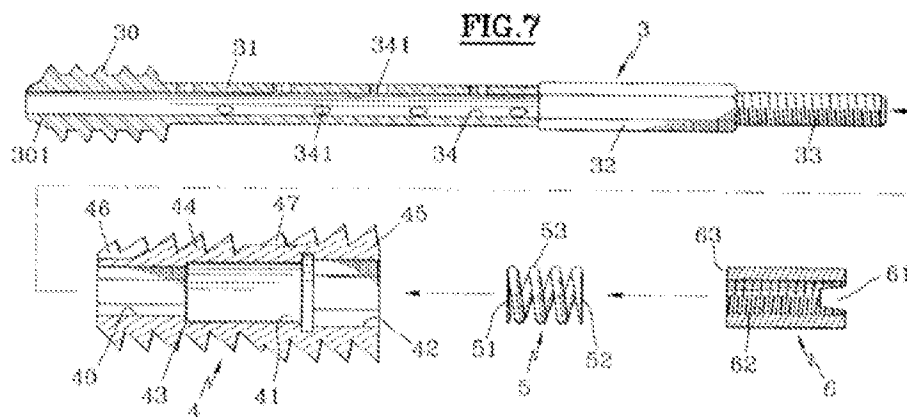
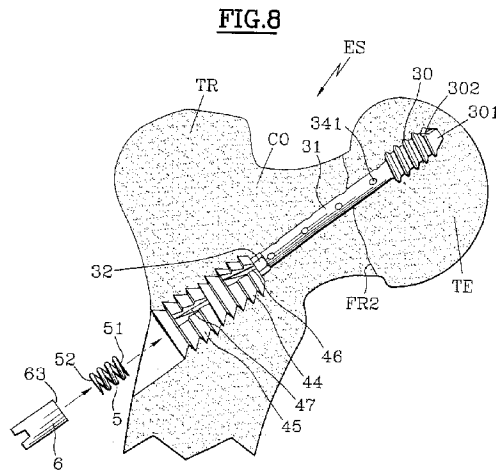


Figure 8 of Lahille, which is reproduced below to facilitate review, illustrates the body (3) and end-piece (4) of the second implant disposed near an end of a fractured proximal femur, before compression through installation of spring 5 and plug 6. The second implant is disposed in threaded engagement with discrete fragments of the femur, on respective opposing sides of a fracture FR2 in a neck of the femur. More particularly, body (3) is disposed in threaded engagement a head fragment of the femur and end-piece (4) is disposed in threaded engagement with a main fragment of the

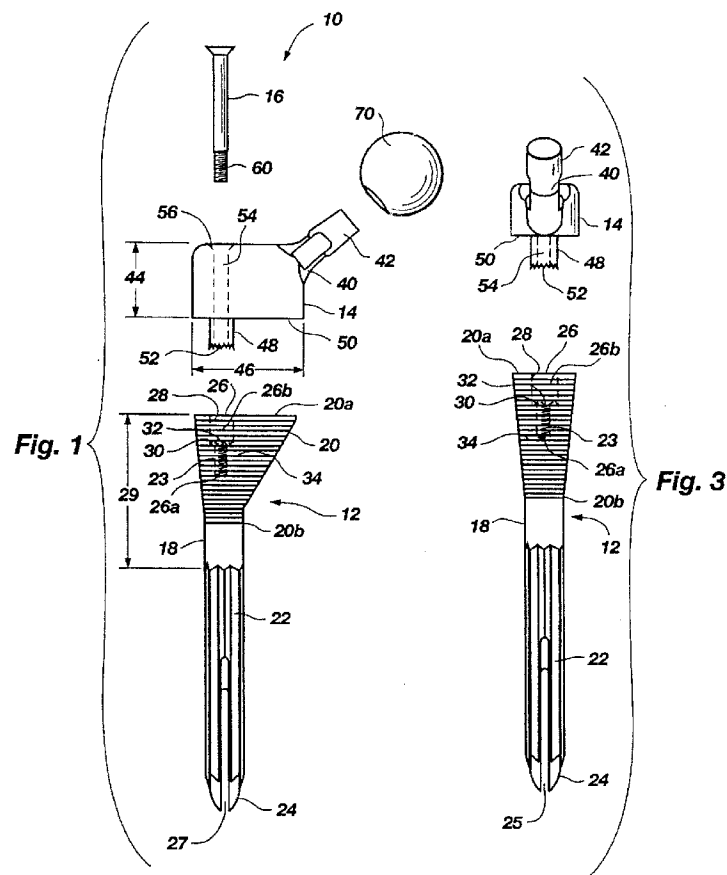
femur. Accordingly, end-piece 4 is locked to the main fragment of the femur, which restricts the end-piece from backing out of the femur, whether or not spring 5 is under compression and whether or not body 3 maintains its engagement with bone.



McTighe involves a modular prosthesis for the hip. Figures 1 and 3 of the reference, which are reproduced below to facilitate review, illustrate an embodiment of the prosthesis (10) in respective side and front views. Prosthesis 10 includes an elongate stem member 12 and a proximal shoulder 14 that is fastened to the stem member by a locking screw 16. The proximal shoulder provides a mounting piece for a hip ball 70.

Stem member 12 includes a shaft 18 and a collar 20 disposed at a proximal end of the shaft. Collar 20 has “a generally ellipsoidal shape, and a series of generally elliptical terraces 34 define the contour of an outer surface of the collar 20.” McTighe, column 4, lines 6-8. Terraces 34 thus are not circular and, furthermore, are not centered on the shaft. Consistent with the noncircular, noncentered characteristics of the terraces, McTighe further states that “the terraces 34 are forced into engagement with

the surrounding intra medullary bone 84 to block *rotational movement* of the stem 12.”
 McTighe, column 4, lines 52-54, emphasis added. Therefore, appellants contend that
 the main functions of collar 20/terraces 34 are (1) to provide a site for connecting
 proximal shoulder 14 and its mounted ball 70 to stem member 12, and (2) to prevent the
 stem member from turning about its long axis.



The Examiner proposed a substantial modification of Lahille's second implant to
 achieve the invention of claim 5 and to permit installation of the modified implant without
 damaging bone. In the proposed modification, Lahille's end-piece 4 and its external
 thread would be replaced by collar 20 of McTighe's stem member 12, to incorporate
 terraces 34 into Lahille's second implant. Also, the Examiner stated that collar 20

(and/or terraces 34) would be modified structurally since “one of ordinary skill in the art would recognize that the shoulders would need to be conformed to the outer circumference of Lahille et al.” Final Office Action, June 11, 2008, page 7, last two lines. Accordingly, in the proposed modification, (a) terraces 34 would be reshaped from elliptical to circular and (b) each circularized terrace 34 would be centered on the central axis of stem member 12. In other words, the Examiner proposed a non-obvious, fundamental re-design of collar 20 in order to meet the limitations of claim 5.

3. No Rational Articulation for the Proposed Modification

To establish *prima facie* obviousness, the Examiner must provide a rational articulation of why one of ordinary skill in the art would be motivated to make the proposed modification. The Examiner has failed to provide a rational articulation for the reasons set forth below.

The Examiner provided the following motivations for the proposed modification: “in order to achieve the predictable result of compression. Furthermore, the device of Lahille et al. would gain the additional benefits of rotational stability and stimulation of bone growth (column 4, lines 46-62).” Final Office Action, June 11, 2008, page 5, last four lines.

Appellants disagree. None of the alleged motivations for the proposed modification of Lahille with McTighe provides any apparent benefit of modified collar 20, with modified terraces 34, over the use of an external thread on end-piece 4. Instead, the proposed modification provides a substantial disadvantage. In particular, the rotation stability offered by the offset elliptical terraces 34 of collar 20 is eliminated when terraces 34 are circularized and centered on the shaft of Lahille’s second implant, as

proposed by the Examiner. Accordingly, there is motivation not to introduce the modified collar/modified terraces proposed by the Examiner because, once circularized and centered, the terraces would provide substantially less rotational stability than the external thread of end-piece 4. Also, there is no disclosure or suggestion that the reduced rotational stability provided by modified collar 20 would be offset by any improvement in compression or by any better stimulation of bone growth than end-piece 4 of Lahille.

In summary, the Examiner has not met his burden to provide a rational articulation for the proposed modification.

4. *Lahille Teaches Away from the Proposed Modification*

End-piece 4 of Lahille incorporates two screwthreaded sections 44, 45 of distinct pitch (Figures 7 and 8). Lahille states that the difference in pitch “between the two screwthreaded sections 44 and 45 *prevents unscrewing* of the end-piece 4.” Lahille, column 9, lines 59-61, emphasis added. In other words, Lahille teaches the importance of locking end-piece 4 in bone, not just with one threaded region, but through engagement of two screwthreaded sections 44, 45 with bone. Lahille thus effectively teaches away from any configuration of end-piece 4 in which the end-piece would not be locked to bone and could potentially back out of the main fragment of the femur.

The proposed modification of Lahille replaces (i) end-piece 4 that locks directly to bone with (ii) a modified collar 20 from McTighe that does not lock directly to bone. Accordingly, the proposed modification of Lahille’s second implant does not fix the position of the modified collar with respect to the main fragment of the femur. As a result, modified collar 20 from McTighe is capable of backing out of bone, which runs

counter to the teaching of Lahille. Furthermore, one of ordinary skill in the art would have considered the proposed modification to provide an inferior implant that is less stably seated in bone than the second implant of Lahille.

5. *The Proposed Modification Changes the Principle of Operation of Lahille*

Lahille functions by locking the second implant to each member of a pair of bone fragments on opposing sides of a fracture. The proposed modification would change how the implant of Lahille functions by relying exclusively on axial tension to restrict slippage of the head (i.e., modified collar 20) of the implant relative to its engaged bone fragment.

6. *The Proposed Modification Requires Nonobvious Changes to Collar 20*

The proposed modification requires that collar 20 be changed substantially in function and structure. Appellants contend that these fundamental changes to the collar, to its connection to other elements, and to its use would have been nonobvious to one of ordinary skill in the art, as detailed below.

Collar 20 provides a proximal end of a stem member for a hip prosthesis. It would not have been obvious to transfer collar 20 from a prosthesis to a very different type of orthopedic implant, namely, a bone screw.

Collar 20 supports a prosthetic head. It would not have been obvious to use collar 20 as the head of a bone screw and in isolation from any other prosthetic elements.

Collar 20 restricts rotational movement of the stem. It would not have been obvious to circularize and center the collar such that the collar permits rotational motion of a bone screw.

Collar 20 extends longitudinally in the bone's medullary canal to a position near the (prosthetic) head of the bone. It would not have been obvious to place collar 20 transverse to the medullary canal and opposing the head of the bone, as in Figure 8 of Lahille.

7. Summary

The Examiner, for at least the reasons presented above, has not established *prima facie* obviousness of claim 5 over a combination of Lahille and McTighe. Therefore, rejection of claim 5 for obviousness over the cited references should be reversed. Rejection of claims 6–9, 11, 13–15, and 17–20, which depend from claim 5, also should be reversed for at least the same reasons as claim 5.

D. Claims 21–26, 28, and 31–40

Each of claims 21–26, 28, and 31–40 was rejected as being obvious over a combination of Lahille and McTighe, based on the proposed modification described above. Therefore, there is no *prima facie* obviousness for any of claims 21–26, 28, and 31–40, for at least the same reasons as those presented above for claim 5.

E. Conclusion

For at least the reasons stated above, appellants believe that all of the claims under appeal are patentable over a combination of Lahille and McTighe. Accordingly, appellants submit that the rejection of claims 5–9, 11, 13–15, 17–26, 28, and 31–40 under 35 U.S.C. § 103 is improper and should be reversed.

VIII. CLAIMS APPENDIX

5. A method of compressing a bone, comprising:

selecting a bone screw including

a shank including a thread disposed externally for threaded engagement with bone, the shank defining a long axis and a direction of advancement into bone, and

a head connected to the shank and defining a plurality of shoulders disposed at spaced positions generally along the head, each shoulder facing generally toward the direction of advancement and extending partially or completely around the head to define a respective plane disposed orthogonally to the long axis; and

installing the bone screw as a unit in a bone such that a portion of the bone near the head is engaged by two or more of the shoulders and is urged toward a portion of the bone near the shank.

6. The method of claim 5, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which the shank has a proximal portion adjacent the head and a distal portion spaced from the head, and wherein the thread is restricted to the distal portion.

7. The method of claim 5, wherein the step of selecting a bone screw includes a step of selecting a bone screw that is self-tapping.

8. The method of claim 5, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which the shank includes a tip region configured to cut a hole in the bone as the bone screw is advanced into the bone.

9. The method of claim 5, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which the shoulders are formed by a plurality of ridges, a plurality of grooves, or both.

11. The method of claim 5, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which one or more of the plurality of shoulders extend in a closed loop corresponding to a circle.

13. The method of claim 5, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which the plurality of shoulders have a corresponding plurality of diameters, and wherein the diameters decrease successively toward the shank.

14. The method of claim 5, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which the head is shaped generally as a frustum of a cone.

15. The method of claim 5, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which the head includes a plurality of steps defined by stepwise decreases in the diameter of the head, and wherein the plurality of shoulders are included in the plurality of steps.

17. The method of claim 5, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which the shank and the head define

opposing ends of the bone screw and further define an axial bore extending between the opposing ends.

18. The method of claim 17, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which the axial bore includes a widened region configured to receive a tool that engages the head.

19. The method of claim 5, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which the head and the shank are both part of the same monolithic structure.

20. The method of claim 5, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which the head is rotatably and/or slidably connected to the shank.

21. A method of compressing a bone, comprising:

selecting a bone screw including

a shank including a proximal region, a distal region, and a thread disposed externally for threaded engagement with bone and restricted to the distal region, and

a head connected to the shank and spaced from the thread by the proximal region, the head defining a plurality of spaced shoulders disposed generally along the head, each shoulder extending in a respective plane to describe at least an arc of a circle; and

installing the bone screw as a unit in a bone such that a portion of the bone near the head is engaged by two or more of the shoulders and is urged toward a portion of the bone near the shank.

22. The method of claim 21, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which the shoulders are defined by a plurality of ridges, a plurality of grooves, or both.

23. The method of claim 21, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which the shoulders describe complete circles.

24. The method of claim 21, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which the head includes a plurality of steps defined by stepwise decreases in the diameter of the head, and wherein the plurality of shoulders are included in the plurality of steps.

25. The method of claim 21, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which the head is generally frustoconical in shape.

26. The method of claim 21, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which the shank defines a long axis, wherein the head has a maximum diameter, wherein the head has an axial length that is measured parallel to the long axis, wherein the head has an aspect ratio defined by the axial length of the head relative to the maximum diameter of the head, and wherein the aspect ratio is at least 1:1.

28. A method of compressing a bone with a bone screw, comprising:

forming a hole in the bone;

selecting a bone screw having a shank and a head connected to the shank, the head defining a plurality of shoulders disposed at spaced positions generally along the

head, each shoulder facing generally toward the direction of advancement and extending partially or completely around the head to define a respective plane disposed orthogonally to the long axis; and

advancing first the shank and then the head of the bone screw into the hole via threaded engagement of the shank with the bone such that a portion of the bone near the head is engaged by two or more of the shoulders and is urged toward a portion of the bone near the shank.

31. The method of claim 28, wherein the step of forming a hole includes a step of forming a bore and a counterbore, and wherein the step of advancing disposes the head and the shank at least substantially in the counterbore and the bore, respectively.

32. The method of claim 28, wherein the step of forming a hole is performed by the step of advancing.

33. The method of claim 28, wherein the portion of the bone near the head and the portion of the bone near the shank are separated by a fracture in the bone.

34. The method of claim 5, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which one or more of the shoulders slope radially outward, generally toward the direction of advancement into bone.

35. A method of compressing a bone, comprising:

selecting a bone screw including

a shank including a thread disposed externally for threaded engagement with bone, the shank defining a long axis and a direction of advancement into bone, and

a head connected to the shank and including a plurality of spaced shoulders of different diameter, each shoulder facing generally toward the direction of advancement and extending partially or completely around the long axis in a respective path defining a plane; and

installing the bone screw as a unit in a bone such that a portion of the bone near the head is engaged by two or more of the shoulders and is urged toward a portion of the bone near the shank.

36. The method of claim 35, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which each shoulder follows a respective path defining a plane oriented orthogonally to the long axis.

37. The method of claim 35, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which each shoulder follows a respective path corresponding to at least an arc of a circle.

38. The method of claim 35, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which each shoulder extends completely around the long axis in a closed loop.

39. The method of claim 35, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which each shoulder slopes radially outward, generally toward the direction of advancement into bone.

40. The method of claim 35, wherein the step of selecting a bone screw includes a step of selecting a bone screw in which the head includes at least one generally cylindrical segment disposed at least partially between a pair of the shoulders.

IX. EVIDENCE APPENDIX

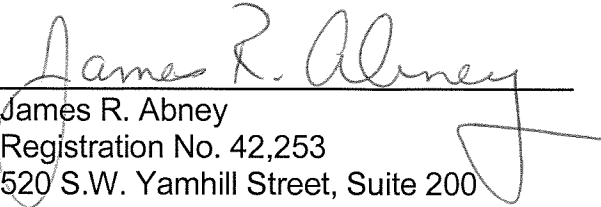
None.

X. RELATED PROCEEDINGS APPENDIX

None.

Respectfully submitted,

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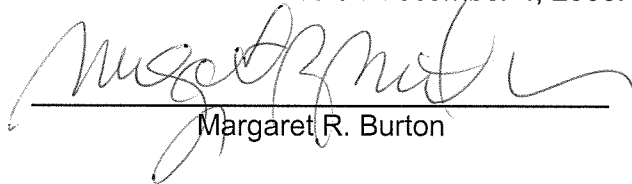
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CERTIFICATE OF ELECTRONIC FILING

I hereby certify that this correspondence is being submitted via the EFS-Web Electronic Filing System to the U.S. Patent and Trademark Office on December 4, 2008.



Margaret R. Burton